Amendments to the Specification:

Please replace the SUMMARY section beginning on page 2, line 11 and ending on page 4, line 6 with the following SUMMARY corresponding to the claims:

--The present invention provides an apparatus and method for analyzing a fluid sample to determine the presence or absence of an analyte in the sample. The apparatus includes a cartridge for separating a desired analyte from the sample and for holding the analyte for a chemical reaction and optical detection. The apparatus also includes an instrument for receiving the cartridge for sample processing. The desired analyte may comprise, e.g., organisms, cells, proteins, nucleic acid, carbohydrates, virus particles, bacteria, chemicals, or biochemicals. In a preferred use, the desired analyte comprises nucleic acid and the chemical reaction performed is nucleic acid amplification using, e.g., the polymerase chain reaction (PCR).

In accordance with an aspect of the present invention, a device for conducting a chemical reaction comprises a body having at least first and second channels formed therein. A reaction vessel extends from the body, the reaction vessel having a reaction chamber, an inlet port connected to the reaction chamber via an inlet channel, and an outlet port connected to the reaction chamber via an outlet channel. The inlet port of the vessel is connected to the first channel in the body, the outlet port of the vessel is connected to the second channel in the body, and the body further includes a vent in fluid communication with the second channel for venting gas from the second channel.

In accordance with another aspect of the present invention, a device for conducting a chemical reaction comprises a body having at least first and second channels formed therein. A reaction vessel extends from the body, the reaction vessel having a rigid frame defining side walls of a reaction chamber, first and second polymeric films attached to opposite sides of the rigid frame to form opposing major walls of the reaction chamber, an inlet port connected to the reaction chamber via an inlet channel, and an outlet port connected to the reaction chamber via an outlet channel. The inlet port of the vessel is connected to the first channel in the body, and the outlet port of the vessel is connected to the second channel in the body.

In accordance with another aspect of the present invention, a device for conducting a chemical reaction comprises a body having a sample flow path and having a separation region in

the sample flow path for separating a desired analyte from a fluid sample. A reaction vessel extends from the body, the reaction vessel having a reaction chamber, an inlet port connected to the reaction chamber via an inlet channel, and an outlet port connected to the reaction chamber via an outlet channel. The body further has at least first and second channels formed therein, the separation region being connected to the inlet port of the vessel via the first channel in the body, and the outlet port of the vessel being connected to the second channel in the body.

In accordance with another aspect of the present invention, a device for conducting a chemical reaction comprises a body having at least first and second channels formed therein. A reaction vessel extends from the body, the reaction vessel having a plurality of walls defining a reaction chamber. At least one of the walls comprising a flexible sheet or film. The vessel also has an inlet port connected to the reaction chamber via an inlet channel and an outlet port connected to the reaction chamber via an outlet channel. The inlet port of the vessel is connected to the first channel in the body, and the outlet port of the vessel is connected to the second channel in the body. The device also comprises at least one thermal surface for contacting the sheet or film, means for increasing the pressure in the reaction chamber, wherein the pressure increase in the chamber is sufficient to force the sheet or film to conform to the thermal surface, and at least one thermal element for heating or cooling the surface to induce a temperature change in the chamber.

In accordance with another aspect of the present invention, a device for conducting a chemical reaction comprises a body having at least first and second channels formed therein. A reaction vessel extends from the body, the reaction vessel having a reaction chamber defined by two opposing major walls and side walls connecting the major walls to each other. At least two of the walls defining the reaction chamber are optically transmissive. The reaction vessel also has an inlet port connected to the reaction chamber via an inlet channel and an outlet port connected to the reaction chamber via an outlet channel. The inlet port of the vessel is connected to the first channel in the body, and the outlet port of the vessel is connected to the second channel in the body. The device also comprises optics for optically interrogating the reaction chamber, the optics comprising at least one light source for transmitting light to the reaction chamber through a first one of the optically transmissive walls and at least one detector for detecting light exiting the chamber through a second one of the optically transmissive walls.

Another aspect of the invention is a method for conducting a chemical reaction, the method comprising the step of introducing a sample into a device comprising a body having a sample flow path and having a separation region in the sample flow path for separating a desired analyte from the sample. The device also comprises a reaction vessel extending from the body, the reaction vessel having a reaction chamber, an inlet port connected to the reaction chamber via an inlet channel, and an outlet port connected to the reaction chamber via an outlet channel. The body further has a first channel connected to the inlet port of the vessel and a second channel connected to the outlet port of the vessel. The method also comprises the steps of separating the analyte from the sample in the separation region, forcing the analyte to flow into the reaction chamber of the vessel via the first channel in the body while air displaced from the reaction chamber exits through the outlet channel and outlet port of the vessel into the second channel in the body, and conducting a chemical reaction in the reaction chamber.

[In a preferred embodiment, the cartridge comprises a body having at least one flow path formed therein. The cartridge also includes a reaction vessel extending from the body for holding a reaction mixture for chemical reaction and optical detection. The vessel comprises a rigid frame defining the side walls of a reaction chamber. The frame includes at least one channel connecting the flow path to the chamber. The vessel also includes at least one flexible film or sheet attached to the rigid frame to form a major wall of the chamber. The major wall is sufficiently flexible to conform to a thermal surface. Preferably, the vessel includes first and second flexible sheets attached to opposite sides of the rigid frame to form opposing major walls of the chamber. In addition, at least two of the side walls are optically transmissive and angularly offset from each other by about 90°.

The cartridge is preferably used in combination with an instrument having opposing thermal plates positioned to receive the chamber between them. The instrument also includes a pressure source for increasing the pressure in the reaction chamber. The pressure increase in the chamber is sufficient to force the major walls to contact and conform to the surfaces of the plates, ensuring optimal thermal conduction to the reaction chamber. The instrument also includes heating elements disposed on the plates for rapid thermal processing of the reaction mixture. The instrument further includes an optics system having at least one light source for exciting the reaction mixture in the chamber through a first one of the optically

transmissive side walls and having at least one detector for detecting light emitted from the chamber through a second one of the optically transmissive side walls.

The cartridge of the present invention permits extremely rapid heating and cooling of the reaction mixture, ensures optimal thermal transfer between the mixture and heating or cooling elements, provides real-time optical detection and monitoring of reaction products with increased detection sensitivity

A greater understanding of the invention may be gained by considering the following detailed description and the accompanying drawings.]--